K011047

JUN 2 8 2001

DePuy
a Johnson&Johnson company

510(k) SUMMARY

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(K) CONTACT:	Marcia Arentz, RAC Sr. Regulatory Associate DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988
TRADE NAME:	Global® Advantage Humeral Stem with Porocoat®
COMMON NAME:	Shoulder prosthesis
CLASSIFICATION:	Class II per 21 CFR, 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis. Class II per 21 CFR 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis
DEVICE PRODUCT CODE:	87 MBF, 87 KWS
SUBSTANTIALLY EQUIVALENT DEVICES:	**DePuy** Global® Advantage Shoulder K992065 DePuy Porous Coated Global Shoulder K943300

DEVICE DESCRIPTION:
The humeral stems are made from titanium alloy and are porous-coated with commercially pure titanium. The stems are available in ten sizes: six standard length stems and four long stems. They are similar in design to the Global Advantage Humeral Stems cleared in K992065 on July 12, 1999. with the addition of Porocoat® porous coating applied to the proximal portion of the stem.

INDICATIONS AND INTENDED USE:

Intended Use:
The subject humeral stems are for use in total or hemi-shoulder replacement. The subject humeral stems are intended for cemented or cementless use, with fixation provided by biological tissue ingrowth into the porous coating.

Indications:

Total or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).
4. Rotator cuff tear arthropathy.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on similarities in design, indications for use, and materials, the subject humeral stems are substantially equivalent to the predicate Global Advantage Humeral Stems cleared in K992065 and the Porous Coated Global Shoulder cleared in K943300.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2001

Ms. Marcia J. Arentz, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K011047
Trade Name: Global® Advantage Humeral Stem with Porocoat®
Regulation Number: 21 CFR 888.3670
Regulatory Class: II
Product Code: MBF
Dated: April 5, 2001
Received: April 6, 2001

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Ms. Marcia J. Arentz, RAC

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DePuy
a Johnson & Johnson company

INDICATIONS

510(k) Premarket Notification

510(k) Number (if known) K011047

Device Name: **Global® Advantage Humeral Stem with Porocoat®**

Indications for Use:

Total or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).
4. Rotator cuff tear arthropathy.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.

Porocoat® Porous-Coated Components
Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue ingrowth into the porous coating.

Cemented Components
Humeral stem and Glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

Press-fit or Cemented Components
Humeral stem prostheses without porous coating and labeled "for press fit or cemented us only" are indicated for press-fit uncemented use or for use with bone cement.

Concurrence of CDRH, Office of Device Evaluation:

Prescription Use X or Over-The-Counter Use ___ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011047